

## HUMAN RESEARCH PROTECTION PROGRAM

1. PURPOSE. To establish policy and procedure for the Human Research Protection Program (HRPP).
2. POLICY. The HRPP is a comprehensive program ensuring the protection of human subjects participating in research. The HRPP strictly adheres to the regulatory authority and research related ethical principles as outlined in VHA Handbook 1200.5 and all other Federal and VA regulations.
3. DEFINITIONS.
  - a. Research and Development Committee (R&D): The committee responsible for promulgating and maintaining the high standards of ethical conduct necessary to protect human research subjects. This committee approves all human subject research protocols conducted under the auspices of the VA including research on the VA premises, using veteran subjects, using VA resources, or involving VA staff. The ACOS/R and appropriate R&D subcommittees considers the impact of VA resources during their review of projects and make recommendations to the R&D Committee. The R&D Committee addresses any conflicts of interest related to research. No research is conducted without R&D Committee approval. The R&D Committee has oversight over all VA investigators.
  - b. Subcommittee for Research Safety: The subcommittee responsible for coordinating the safety program as it relates to research activities.
  - c. Institutional Review Board (IRB): The University of Florida's Health Science Center IRB-01 that serves as the system's affiliate IRB. This IRB is responsible for scientific review and approval of all human studies research conducted on VA premises. This affiliation is officially recognized by the Memorandum of Understanding (MOU) between the two institutions.
  - d. IRB Standard Operating Procedures (SOP): The web based on-line manual for all individuals involved with human subject research describing the IRB's structure, function, procedures and research oversight.
  - e. Memorandum of Understanding (MOU): The official agreement between the University of Florida and the NF/SGVHS for use of the academic affiliate IRB-01 to ensure protection of human subjects for VA research. The MOU stipulates that the IRB-01 will adhere to all Federal and VA regulations governing research and human subject protection.

### 3. DEFINITIONS (continued)

f. Federal Wide Assurance (FWA): The written assurance between the NF/SGVHS and the Department of Health and Human Services that all research conducted on the VA premises will comply with 45 CFR 46 as stipulated in the Terms of Assurance for Protection of Human Subjects within the United States.

g. Oversight Committee on Clinical Research (OCCR): OCCR will perform Quality Assurance (QA) reviews for human subjects research performed at NF/SGVHS to ensure quality of the HRPP. The results of the QA reviews will be communicated to the R&D Committee. As a matter of process, OCCR will make recommendations to the R&D Committee and to the Research Office regarding successful processes or identified deficiencies. Identified deficiencies will be reported to the appropriate committee(s) as needed. OCCR also monitors research practices of local VA investigators and applicable research committees in an effort to ensure compliance of human research projects with applicable laws, regulations and guidance.

h. Investigation Drug Service (IDS): The service that controls all investigational drug use including storage, dispensing and administration. The service also provides investigational drug education to VA staff and evaluates all research related adverse drug events.

i. Investigator's Human Subject Research Standard Operating Procedures and Resources: The Research Service's web based reference manual for all individuals involved with VA human subject research including policies and procedures unique to the VA and/or relating to the HRPP. <http://www.northflorida.va.gov/Research/indexResearchers.asp>

j. Investigational Drug Service Manual: The IDS manual for all individuals involved with investigational drugs. The manual outlines VA policy and procedures related to investigational drug storage, dispensing, and administration.

k. Radiation Safety Committee: The committee responsible for oversight of all ionizing radiation and radionuclide usage in NF/SGVHS.

l. Federal Drug Administration (FDA): Agency assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation

m. Office Human Research Protection (OHRP): Agency assuring compliance with federal human subject research regulations under the auspices of the Department of Health and Human Services.

n. Principal Investigator (PI and also known as a clinical investigator): A VA credentialed researcher conducting scientific studies who may lead a team of individuals including other investigators

### 4. PROCEDURE.

a. The HRPP functions through the activities and standard operating procedures as defined above.

b. Request for Approval: Any professional within the System who plans to conduct investigational studies involving VA patients, staff, facilities or medical records must submit, in writing, copies of

the investigational proposal to the Compliance Core Program Assistant for Human Subjects in Research Service in compliance with current submission guidelines.

c. All meeting minutes are maintained in Research Service.

d. The R&D Committee reports to the Director important findings or recommendations regarding the protection of human research subjects as part of the HRPP. Minutes and/or substantive findings from the committees below are reviewed by the R&D committee:

- (1) Subcommittee for Research Safety (SRS)
- (2) Academic Affiliate IRB-01
- (3) Oversight Committee on Clinical Research (OCCR)

e. The HRPP through Research Service makes available human subject protection training that meets VA and Federal requirements;

(1) All VA investigators, Research Coordinators, Research Assistants, and R and D Committee members and sub-committee members must submit updated training course certificates to Research Service as mandated by VA guidance.

(2) Training in human subject protection and Good Clinical Practice must be maintained according to VA regulations. A combined course that consolidates the two courses into one is available through the CITI (Collaborative IRB Training Initiatives) <http://citiprogram.org/> and meets the mandatory requirements.

(3) Research Service audits training records ensuring that individuals have met their educational requirements.

f. Any employee, human subject, community member, or the academic affiliated IRB may report complaints or allegations of non-compliance to Research Service, Research Compliance Officer (RCO) or any member of the OCCR committee.

## 5. RESPONSIBILITY.

a. The Director is the VA Institutional Official responsible for ensuring the integrity and operations of the HRPP including oversight of the IRB and all VA investigators and is the point of contact for all OHRP, FDA, and VA Central Office research related correspondence.


b. The Associate Chief of Staff for Research (ACOS/R) is responsible for coordination and oversight of the activities of the HRPP and for dissemination of education regarding human subject research protection.

c. Investigators are responsible for adhering to this policy and for ensuring the protection of human subjects participating in research.

d. Members of the R&D Committee and its subcommittees are responsible for oversight of the activities of the HRPP.

## 6. REFERENCES.

- a. VHA Handbook 1200.5, Requirements for the Protection of Human Subjects Research
  - b. National Institutes of Health, Office of Human Subjects (<http://ohsr.od.nih.gov>)
  - c. National Cancer Institute Human Participant Protections Education for Research Teams (<http://cme.nci.nih.gov/>)
  - d. CITI (Collaborative IRB Training Initiatives) The Protection of Human Research Subjects <http://citiprogram.org/>
  - e. HRPP Investigator Manual: SOP for The Protection of Human Subjects in Research, <http://www.northflorida.va.gov/research/policies.asp>
7. RESCISSION. Memorandum No. 151-3, Change 4, dated July 11, 2006.
  8. EXPIRATION DATE. February 23, 2012.
  9. FOLLOW-UP RESPONSIBILITY. ACOS for Research and Development.



THOMAS A. CAPPELLO, MPH, FACHE  
Director